DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2015

Covidien
Ms. Karin Desjardins
Manger, Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K143263
Trade/Device Name: Kangaroo™ Connect Enteral Feeding Pump and Kangaroo™ Connect Feeding Sets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZH
Dated: April 27, 2015
Received: April 29, 2015

Dear Ms. Desjardins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143263

Device Name

Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets

Indications for Use *(Describe)*

The Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets delivers nutritional formula to the gastrointestinal system of a patient age Infant and older who is physically unable to eat and swallow. Not for use with neonates. The feeding pump and feeding sets are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: K143263

Kangaroo™ Connect Enteral Feeding Pump and Kangaroo™ Connect Enteral Feeding Sets

In accordance with section 513(i) of the SMDA and as defined in 21CFR Part 807.92 this summary is submitted by:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: May 21, 2015

a. Contact Person

Karin Desjardins
Manager, Regulatory Affairs
Patient Monitoring & Recovery
Medtronic
Telephone: (508) 261-1856
Fax: (508) 261-8461

b. Name of Medical Device

Common Name: Enteral Feeding pump, Infusion pump

U.S. FDA Classification Product Code: LZH

U.S. Regulation Description: Infusion Pump, 21 CFR 880.5725

Proprietary / Trade Name: Kangaroo™ Connect Enteral Feeding Pump and Kangaroo™ Connect Feeding Sets

c. Identification of Legally Marketed Device(s)

Covidien Kangaroo™ ePump Enteral Feeding Pump and Enteral Feeding Set, K040196

d. Device Brief Description

The table below provides a comparison of the key attributes of the predicate and proposed devices.

Device Comparison Summary		
	Predicate Device (K040196)	**Proposed Device (K143263)**
Device Name	Kangaroo™ e-pump	Kangaroo™ Connect Enteral Feeding Pump and Kangaroo™ Connect Enteral Feeding Sets
Device Description	Enteral feeding pump and disposable enteral feeding sets	Enteral feeding pump and disposable enteral feeding sets
Intended use	Intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding, pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to a patients gastrointestinal system.	Intended for use in patients age Infant and older with any condition requiring enteral feeding, which can be accomplished by means of an enteral feeding pump and pump set. Not for use with neonates. The feeding pumps and sets are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition to a patient's gastrointestinal system.
Sterility	Includes Sterile and non-sterile feeding sets	Non Sterile feeding sets
Technological Characteristics	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate. The connection to the patient enteral access device is a stepped connector.	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate. The connection to the patient enteral access device is an ENFit Connector compliant to ISO 80369-3.
Design (Pump)	The pump incorporates a menu controlled operating system which contains on board custom software designed to allow the user to set feed rates and volumes as well as other feeding options. The device incorporates ultrasonic sensors to detect the air and blockages in the feeding set.	The pump incorporates a menu controlled operating system which contains on board custom software designed to allow the user to set feed rates and volumes as well as other feeding options. The device incorporates ultrasonic sensors to detect the air and blockages in the feeding set.
Rechargeable battery	nickel cadmium	lithium ion
Graphic display	monochrome	multi-color
Water ingress rating	IPX 1	IP26

Device Comparison Summary		
	Predicate Device (K040196)	**Proposed Device (K143263)**
Design (Feeding set)	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1000ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (24 inch) • Pump interface module (peristaltic tubing) • Tubing from pump to patient connector (66 inches) • Patient connector (stepped connector)	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1000ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (14 inch) • Cassette containing pump interface module (peristaltic tubing) • Tubing from pump to patient connector (66 inches) • Patient connector (ENFit connector compliant to ISO 80369-3)
Includes anti-free flow valve	Yes	Yes
Materials/Chemical composition	Polyvinyl chloride (PVC) • Feeding bags and caps • Tubing • Patient connector Silicone • Peristaltic tubing Polycarbonate • Valve body HDPE • Valve stem LDPE • Dust Cover ABS • Spike Strontium Ferrite / nylon • Set ID magnets	Polyvinyl chloride (PVC) • Feeding bags and caps • Tubing Silicone • Peristaltic tubing • Diaphragm valve Polycarbonate • Cassette body CoPolyester • Patient connector ABS • Spike • Tube holder and Cap Strontium Ferrite / nylon • Set ID magnets

e. Statement of Intended Use

The Kangaroo™ Connect Enteral Feeding Pump with Kangaroo™ Connect Feeding Sets delivers nutritional formula to the gastrointestinal system of a patient age infant and older who is physically unable to eat and swallow. Not for use with neonates. The feeding pump and feeding sets are intended to be used in clinical or home care settings by users ranging from laypersons to physicians.

f. Discussion of Technological Differences

Both proposed and predicate pumps perform the same primary function. The proposed device includes 2 ultrasonic sensors to detect both upstream and downstream occlusions vs. one sensor in the predicate device. Additionally, the pump uses a cassette based feeding set where the silicone tube interface with the rotor is contained within the cassette where the predicate device required the user to stretch tubing around the rotor. The proposed device is smaller and lighter, and has longer battery life. The proposed device has a higher water ingress protection rating in accordance with *ANSI/IEC 60529-2004 Degrees of Protection Provided by Enclosures (IP Code)*. The proposed device does not support feed/flush capability, which exists in the predicate device. The proposed feeding set includes the new ENFit connector which is compliant to ISO 80369-3. This connector is part of an industry wide effort to address misconnections by adopting a uniform connector that has been engineered to meet the objective of IS0 80369-1, small-bore connectors for liquids and gases in healthcare applications - part 1: general requirements

g. Discussion of Nonclinical testing

The following testing was the basis for the substantial evaluation determination:

- Biocompatibility testing of the Kangaroo™ Connect Feeding Sets in accordance with ISO 10993-1:2009, Biological Evaluation of medical Devices- Part 1: Evaluation and Testing has demonstrated the biological safety of parts of the medical device which may indirectly contact the patient, and is consistent with FDA "Draft Guidance for Industry and FDA staff, Use of international Standard ISO 10993 'Biological Evaluation of medical Devices Part 1: Evaluation and Testing," issued on April 23, 2013. In accordance with ISO 10993, the feeding sets are categorized as a surface device (category C), permanent use (< 30 days).

- Cleaning and disinfection instructions and validation documentation.

- Stability testing of the proposed device evaluated the key performance properties of the feeding set after accelerated aging in support of the expiration date which will be applied to the device.

- Human factors testing was conducted to evaluate the usability of the device as well as the ENFit connector.

- Electrical Safety testing was conducted in accordance with applicable IEC standards.

- Software verification and validation testing was completed, as recommended by the FDA guidance document Infusion Pump Total Product Life Cycle.

- The battery was evaluated in accordance with UL 2054, 2nd Edition, household and commercial batteries.

- Evidence was provided to demonstrate the functionality and infusion delivery accuracy of the Kangaroo Connect System with over 35 representative nutritional formulas that might be prescribed.

- Infusion delivery accuracy testing included an evaluation of accuracy at low and high temperatures using low and high viscosity fluids.

- Verification of the fluid ingress protection rating was confirmed on test samples that were preconditioned with mechanical stress tests defined in ANSI/AAMI ED 60601-1. Preconditioning tests included push test, impact test, drop test and mold stress.

- Performance and reliability of the sensors was confirmed when the device is used as labeled.

- A safety assurance case for the Kangaroo Connect Enteral Feeding Pump and Feeding Sets was provided, as recommended by the FDA guidance document, Infusion Pumps Total Product Life Cycle.

h. Clinical testing

Clinical evaluations were not submitted.

i. Conclusions

This information provided within this pre-market notification demonstrates that the Kangaroo™ Connect Enteral Feeding Pump and Kangaroo™ Connect Enteral Feeding Sets are substantially equivalent to the legally marketed predicate device.

End of Summary